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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,753	07/25/2007	Henrik Arnberg	15665-010US1	3748

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EXAMINER	
CHANDRA, GYAN	
ART UNIT	PAPER NUMBER
1646	

NOTIFICATION DATE	DELIVERY MODE
12/28/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/599,753	ARNBERG, HENRIK	
	Examiner	Art Unit	
	GYAN CHANDRA	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *the RCE filed on 14 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,18,21-26 and 32-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,18,21-26 and 32-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/14/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/14/2009 has been entered.

Status of Application, Amendments, And/Or Claims

The amendment of claim 16 and 21, and the addition of claims 32-48 have been made of record.

Claims 16, 18, 21-26 and 32-48 are pending and under examination.

Information Disclosure Statement

The IDS filed on 9/14/2009 has been considered.

Claim Objections

Claim 16 is objected to because of the following informalities:

The Examiner suggests that syntax of claim 16 can be improved by replacing the term "periodontal disease" with the term “a periodontal disease”.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 35 and 36, the sentence is incomplete either by missing a period at the end or part of sentence including a period. Therefore, the metes and bounds of the claims can not be determined.

Response to Arguments

Claim Rejections - 35 USC § 103*-withdrawn*

The rejection of claims under 35 U.S.C. 103(a) as being unpatentable over Gradstein et al (US Patent No. 5,162,111) in view of Grzybowski et al (Int. J. Pharmaceutics 184: 179-187, 1999) and further in view of Sampathkumar (US Patent No. 4,804,530) is withdrawn in view of applicants' arguments and which have been fully considered and are persuasive. However, upon further consideration, a new ground(s) of rejection under 35 USC 102 (b) is made in view of US Patent No. 5,976,523 or US pub. No. 20070105824.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

It is noted to applicants that the Examiner is interpreting that the claim is missing a period at the end.

Claims 16, 22-26, 36-42, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Awaya et al (US patent No. 5,976,523).

The instant claims are broadly drawn to a method of treating a mammal suffering from a periodontal disease or inducing tooth calcification comprising locally administering by injection in the proximity of the periodontal disease a therapeutically effective amount of a composition comprising at least one granulocyte-macrophage-colony stimulating factor (GM-CSF) polypeptide (claim 16), wherein the composition the composition comprises 5-800 ug of GM-CSF per unit dosage (claims 22-23, 38-39), wherein the composition is administered at intervals ranging from once a day to once every third week (claims 24, 40), wherein the composition is administered a total of 1 to 3 times for a period of one week (claims 25, 41), wherein the composition comprises a therapeutically effective amount of at least one other active ingredient (claims 26, 42), wherein the mammal is a human (claims 36, 48).

Awaya et al teach a method for healing compromised tissues, including periodontal damage comprising administering a composition of formula (1) or (2) (see claim 1) and further comprising additional substance selected from a list of growth factors which includes GM-CSF (see claim 15). Therefore, the teachings of Awaya et al

meet the limitations of claims 16, 26, 37 and 42. Awaya et al teach that the composition contains generally 0.1 to 2000 mg per unit dosage form (see col. 9, lines 22-23) which meets the limitations of claims 22, 23, 38 and 39. Awaya et al teach that the suitable number of administration is usually 1 to 4 daily (col. 9, lines 34-35) which meets the limitation of claims 24, 25, 40 and 41. They teach that the amount of the compound can be actually determined by a physician depending upon patient body weight and age etc., which meets the limitation of claims 36 and 48 (col. 9, lines28+). Therefore, the prior art implicitly or explicitly anticipates the instant invention.

Claims 16, 18, 22-26, 36, 37, 40-42, and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Erickson-Miller et al (US pub. No. 20070105824).

The instant claims are broadly drawn to a method of treating a mammal suffering from a periodontal disease or inducing tooth calcification comprising locally administering by injection in the proximity of the periodontal disease a therapeutically effective amount of a composition comprising at least one granulocyte-macrophage-colony stimulating factor (GM-CSF) polypeptide (claim 16), wherein the periodontal disease is gingivitis or periodontitis (claims 18, 37), wherein the composition the composition comprises 5-800 ug of GM-CSF per unit dosage (claims 22-23, 38-39), wherein the composition is administered at intervals ranging from once a day to once every third week (claims 24, 40), wherein the composition is administered a total of 1 to 3 times for a period of one week (claims 25, 41), wherein the composition comprises a

therapeutically effective amount of at least one other active ingredient (claims 26, 42), wherein the mammal is a human (claims 36, 48).

Erickson-Miller et al teach a method of treating degenerative disease/injury selected from periodontal disease, gingivitis, tooth loss and metastatic bone disease (claim 5) in a mammal in need thereof comprising administering a compound selected from claim 10 and further comprising co-administering an agent such as GM-CSF (claim 16). Erickson-Miller et al teach administering a selected dose from 1-6 times daily parenterally or orally [0325]. The teach administering a dose by injection or continuous infusion. They teach that oral dosage units for human administration preferably contain from 0.05 to 3500 mg of active compound [0325]. They teach that optimal dosages to be administered may be readily determined by those skilled in the art [0326]. Therefore, the prior art of record implicitly or explicitly anticipates the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21, 32-35 and 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Awaya et al (US patent No. 5,976,523) in view of O'Uchi et al (US Patent No. 6,682,718); or Erickson-Miller et al (US pub. No. 20070105824) in view of O'Uchi et al (US Patent No. 6,682,718).

The instant claims are broadly drawn to a method of treating a mammal suffering from a periodontal disease by administering a composition comprising GM-CSF wherein the composition is administered by injection through the mucosal lining of the gingiva or application in a periodontal pocket (claims 21, 43), wherein the composition is administered by injection into the alveolar mucosa (claims 32, 44), wherein the composition is administered by injection into the sublingual mucosa (claims 33, 45), wherein the composition is administered by injection into the palate part (claims 34, 46), and wherein the composition is administered by injection between the periosteum of the alveolar bone and the alveolar mucosa (claims 35, 47).

The teachings of Awaya et al or Erickson-Miller et al are summarized as set forth above. Neither Awaya et al nor Erickson-Miller et al teaches injecting a composition through the mucosal lining of the gingiva, into the alveolar mucosa, into the palate part, or between the periosteum of the alveolar bone and the alveolar mucosa.

O'Uchi et al teach periodontitis is a disease in which chronic gingivitis progresses and inflammation is also spread to periodontal tissues other than gingiva, which accompanies progressive destruction of periodontal tissues (col. 1, lines13+). Clinically,

chronic inflammation of gingiva, bleeding from periodontal pockets, alveolar bone resorption and the like are observed, and it is known that mobility and movement of teeth occur as the destruction advances, finally causing spontaneous loss of a tooth or a necessity of tooth extraction (col.1, lines 15+). O'Uchi et al teach that topical injection into periodontal tissues around alveolar bone, namely into gingiva, alveolar mucosa, sublingual mucosa, palate part and the like, is most desirable as a method for transferring a drug to the alveolar bone. However, since the periodontal tissue around the alveolar bone where topical injection of a drug can be actually carried out is very small, the volume that can be administered is limited, and there is a possibility of causing patients a pain, so that further improvement of the administration method is desired (col. 4, lines 25+).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention was made to administer a composition taught by either Awaya et al or Erickson-Miller et al through the mucosal lining of the gingiva, into the alveolar mucosa, into the palate part, or between the periosteum of the alveolar bone and the alveolar mucosa as taught by O'Uchi et al. One of ordinary skill of the art would have been motivated to administer the composition of either et al or Erickson-Miller et al through the mucosal lining of the gingiva, into the alveolar mucosa, into the palate part, or between the periosteum of the alveolar bone and the alveolar mucosa because O'Uchi et al teach that a periodontal disease is chronic gingivitis spreads to periodontal tissues and includes chronic inflammation, bleeding from periodontal pockets or alveolar bone resorption and therefore, one would administer a composition locally in

surrounding areas to be more effective. One would have a reasonable expectation of success in treating a periodontal disease by administering a composition taught by either Awaya et al or Erickson-Miller et al through the mucosal lining of the gingiva, into the alveolar mucosa, into the palate part, or between the periosteum of the alveolar bone and the alveolar mucosa because the said administration method would be in surrounding areas of said periodontal disease and thereby more effective. Thus, the invention as instantly claimed is prima facie obvious in view of combined teachings of the prior art of record.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gyan Chandra/
Examiner, Art Unit 1646